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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,542	01/18/2002	Roberto Reniero	112843-032	7122

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,542

Applicant(s)

RENIERO ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are presented for examination on the merits.

The Preliminary Amendment has been received and entered.

Information Disclosure Statement

The information disclosure statement (IDS)(s) submitted has/have been received
The submission(s) is/are in compliance with the provisions of 37 CFR 1.97.
Accordingly, the information disclosure statement is/are being considered by the
examiner.

Abstract

The abstract of the disclosure is objected to because the abstract does not fully
describe the complete disclosure in less than 150 words using more than one sentence.
The abstract should be comprised of a concise paragraph using at least two to three
complete sentences but be less than 150 words. A more complete abstract is
suggested and the current abstract appears to warrant correction. See MPEP
§ 608.01(b).

Specification

The specification is objected to because it does not set forth clear distinctions
between the sections of the disclosure in accordance with the following arrangement
(note that a Brief Description of the Drawings heading is required of a specification
when drawings are part of the disclosure and it is noted that a heading of "In the
drawings" is used but this title is not preferred):

The following guidelines illustrate the preferred layout for the specification of a
utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-6 are directed to a microorganism which occurs in nature and thus, the claims are not deemed to be patentable subject matter since they read on microorganisms which occur in nature. Lactic acid bacteria are prevalent in the gut of animals and bacterial microorganisms are not patentable unless they have been isolated from nature and determined to possess characteristics which distinguish them from those that do occur in nature. It is suggested to insert –A biologically pure culture— in claim 1 at line 1 before “Lactic acid bacterium”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth

in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to

obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the recitation of “the genus” and “the ability” at line which lack antecedent basis. Also it is unclear whether the bacterium is a strain of Lactobacillus or another species entirely. Thus, it is suggested to before “Lactic acid bacterium” insert —A biologically pure culture of—lactic acid bacterium and then insert after “bacterium” —strain—at line 1. Further, “the intestine” recited at line 2 lacks antecedent basis.

Claims 2-6 lack antecedent basis for the recitation of “The Lactobacillus strain” at line 1. Further, in claim 2 the term “the intestinal mucosa” recited at line 1-2 lacks antecedent basis. Also “and essentially colonize it” is unclear and it is suggested to change phrase to —and colonize said intestinal mucosa--.

Claims 7-10 lack antecedent basis for the usage of terms as described above. Further, in claim 10 the term “the ingestable support material” also lacks antecedent basis. It is suggested to insert —material—in claim 9, line 1, after “ingestable support”. Also 7-10 further are rendered vague and indefinite for failing to set forth clear and distinct process steps.

Claims 11 and 13 are rendered vague and indefinite for lacking antecedent basis for various similar terms as discussed above. For example, “the treatment” at line 1 lacks antecedent basis as does “the step”, and “the genus”, “the intestine”, etc. In addition, the claim is vague and unclear because it fails to set forth how “administering” is being carried out. The claims fails to set forth clear and distinct process steps. Is it parenterally, orally or what? The metes and bounds of the claim can not be determined.

Claim 12 is vague and indefinite in that it is unclear that in the form of composition as claimed is different from a supernatant or the bacterium since no other ingredient is considered as part of the composition. Is a carrier intended to be included? The metes and bounds of the claim can not be determined.

Claims 14-18 lack antecedent basis for usage of several terms as described above for similarly rejected terms in the claims. However, claim 15 is additionally rendered vague and indefinite for being grammatically indefinite since "is capable to grow" is not clear. It is suggested to change the phrase to --grows--.

Claim 20 lacks antecedent basis for usage of similar terminology already discussed above and further the claim fails to set forth a positive and clear step for "administering" for reasons discussed above.

Claim 21 is for antecedent basis issues as discussed above for similar terms and also because the type of food is uncertain. The metes and bounds of the claim can not be determined.

Claims not discussed above are rejected because they depend from rejected base claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/936,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the identical *Lactobacillus* strain for which is used in various treatments and products for purposes of alleviating diarrhea, etc., albeit a different scope wherein the copending claims do not appear to read on treating and prevention pathogenic rotoviruses. However, such pathogenic organisms are well recognized in the prior art and *Lactobacillus* strains and varied species are well known to treat and prevent pathogenic microorganisms. Therefore, one of ordinary skill in the art would have been motivated by the copending claims to provide for the claimed subject matter herein. The claims of the instant case are clearly obvious over the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 09/936,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass

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the identical Lactobacillus strain for which is used in various treatments and products for purposes such as treating diarrhea, et c., albeit a different scope wherein the copending claims do not appear to read on preventing colonization of the intestine with pathogenic bacteria and rotoviruses; thus, the methods and products of the instant claims are very close and similar to the copending methods and products, however, they are not identical because of a difference in their scope. However, they are very similar and one of skill would have been motivated to provide for the instant methods and products from the copending methods and products. Therefore, the instant claims are prima facie obvious over the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 861 905 A2, cited on the enclosed PTO-1449 Form.

Claims are drawn to the *Lactobacillus paracasei* (L.p.) strain CNCM I-2116 and compositions thereof.

EP 0 861 905 A2 teaches L. p. strains and compositions thereof. Note the abstract and page 7, all lines.

The claims differ from the EP reference cited above in that the specific strain is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to select for various strains having similar properties and expect successful results. Clearly these L. p. strains are well known in the art for similar uses, i.e. treating diarrhea and intestinal mucosa. Thus, one of skill in the art would have been motivated to select for other strains as well. A side by side comparison of the strains would show that they possess similar if not identical properties with respect to biochemical characteristics that they have in common. The claims are prima facie obvious over the cited art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 861 905 A2, discussed above..

Claims are directed to varied uses of Lactic acid bacteria : treating intestinal muscosa, preparing products useful for the treatment, products containing the Lactobacillus strain.

The EP is discussed above.

The claims appear to be identical to the cited disclosure and are therefore considered to be anticipated by the teachings of the cited reference.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

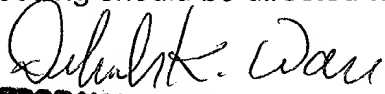
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
September 25, 2003